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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,077	01/04/2002	Terry J. Amiss	P-5430	9417

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EXAMINER	
ALEXANDER, LYLE	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/040,077	AMISS ET AL.
	Examiner	Art Unit
	Lyle A Alexander	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 10-16* is/are rejected.

7)☒ Claim(s) *6-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 and 1-12 of copending Application No. 10/039,833 and 10/039,799 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a biosensor using the same mutated binding protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kratzch et al.

Kratzch et al. teach in paragraph [0008] glucose biosensors using s-GDH(glucose dehydrogenase) are well known in the art. In paragraphs [0002] + teach the instant invention is to creating an improved s-GDH variant by mutating the binding proteins.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hellinga(6,277,627), Hellinga (6,521,446) or Lakowicz et al.

These references all teach use of a mutated protein in combination with a glucose biosensor.

Claims 1-5 and 11-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Marvin et al. (J AM. Chem. Soc. 1998,120,7-1 cite by Applicants), Marvin et al. (Proc. Natl. Acad. Sci. cited by Applicant) or Tolosa (Analytical Biochemistry 267, 114-120(1999) cited by Applicants).

These references all teach glucose biosensors using a mutated binding protein to quantify glucose using fluorescent measurements.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellinga(6,277,627), Hellinga (6,521,446) or Lakowicz et al.

See Hellinga(6,277,627), Hellinga (6,521,446) and Lakowicz et al. supra.

These references are all silent to the claimed positions of amino acid substitution and the claimed luminescent labels.

The court decided In re Boesch (205 USPQ 215) the optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has predictable and well-known results. The choice of label to achieve its well-known and expected function as a label is also a result effective variable.

It would have been within the skill of the art to modify Hellinga(6,277,627), Hellinga (6,521,446) or Lakowicz et al. and modify the claimed amino acids at the claimed positions as optimization of a result effective variable.

The claimed luminescent labels are well known in the art as evidenced the trademarks and copyright notations associated with the labels. For example Quantum Red ™, Texas Red ™, etc. The compounds are well known in the art to perform the function of a fluorescent label and are commercially available. It is desirable to use commercially available labels because they are readily available and accessible to others so the work can be readily duplicated.

It would have been within the skill of the art to further modify Hellinga(6,277,627), Hellinga (6,521,446) or Lakowicz et al. and use well known fluorescent labels, such as Quantum Red ™, Texas Red ™, etc., to gain the above advantages and as optimization of a result effective variable.

Allowable Subject Matter

Claims 6-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 5/26/04 have been fully considered but they are not persuasive.

Applicants' amendments have overcome the 35 USC 112 second paragraph rejections.

Applicants' traverse the provisional obviousness-type double patenting rejections over the two copending application on the basis the two copending applications specifically claim mutated binding proteins and specific means of the proteins attachment. The pending claims specify a mutated binding protein which is indistinguishable from the two-copending applications. Further, the instant claims require attachment of the protein to the reporter group which clearly reads on the attachment claimed by the two-copending applications.

Applicants' traverse the 35 USC 102 rejection over Kratzch '595 on the basis there is no teaching of a reporter group attached to the protein. The Office maintains example 2 and paragraphs [0102] through [0112] disclose attachment of a report group to the protein. (e.g. the claim language of "attached thereto" is sufficiently broad to be read on taught reporter group).

Applicants' traverse the 35 USC 102 rejection over Hellinga('627 or '446) or Lakowicz et al. on the grounds these references fail to teach a reversible signal change upon exposure to varying concentrations of glucose. The Hellinga references teach the sensor using in industrial processes and in vivo which means the sensor would have to be capable of measuring varying glucose concentrations and have a reversible signal change. Lakowicz et al. teach in column 1 lines 61+ " a sensor is not useful for glucose

monitoring unless binding is reversible". Further, column 2 lines 19+ teach measurements of changes in glucose levels which clearly meet the claimed reversibility and subsequent sensitivity to varying concentrations.

Applicants' traverse the 35 USC 102 rejection Marvin et al.(1998) and Tolosa et al. Marvin et al. teach equation(1) that correlates the change in fluorescence to the change in the glucose concentration which is indistinguishable from the claimed reversible/changing signal when exposed to changing glucose concentrations. The Abstract of Tolosa et al. teach the disclosed sensor measures varying glucose concentrations which has been read on the claimed reversible/changing signal when exposed to changing glucose concentrations.

Applicants' traverse the 35 USC 103 rejections over Hellinga(6,277,627), Hellinga (6,521,446) and Lakowicz et al. on the basis of the unobviousness of claim 6. The Office agrees that claim 6 defines over the art of record, but is objected to because it is dependent upon a rejected base claim. The Office maintains the 35 USC 103 rejections of claims 10-16 over Hellinga(6,277,627), Hellinga (6,521,446) and Lakowicz et al. are proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander
Primary Examiner
Art Unit 1743

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